IAP7 Rec'd PCT/PTO 04 AUG 2006

ATTORNEY'S DOCKET NO. TRANSMITTAL LETTER TO THE UNITED STATES 1033935-000020 DESIGNATED/ELECTED OFFICE (DO/EO/US) U.S. APPLICATION No. (If known) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 10/551,094 INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PRIORITY DATE CLAIMED PCT/US2004/009384 26 March 2004 28 March 2003 TITLE OF INVENTION CLADRIBINE FORMULATIONS FOR IMPROVED ORAL AND TRANSMUCOSAL DELIVERY APPLICANT(S) FOR DO/EO/US Nicholas S. Bodor Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: 1. This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. 2. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must 3. include items (5), (6), (9) and (21) indicated below. 4. 🔲 The US has been elected (Article 31). 5. A copy of the International Application as filed (35 U.S.C. 371(c)(2)) a. 🔲 is attached hereto (required only if not communicated by the International Bureau). b. 🔲 has been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). 6. An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)) a. 🔲 is attached hereto. b. 🔲 has been previously submitted under 35 U.S.C. 154(d)(4). 7. \square Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) a. 🗌 are attached hereto (required only if not communicated by the International Bureau). b. □ have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. have not been made and will not be made. 8. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). An English language translation of the annexes of the International Preliminary Examination Report under 10. 🔲 PCT Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 11. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is 12. 🗌 included.

Buchanan Ingersoll & Rooney PC

A preliminary amendment.

A substitute specification.

on September 28, 2005

An Application Data Sheet under 37 CFR 1.76.

A power of attorney and/or change of address letter.

13. 🔲

14. 🔲

15. 🔲

16. 🗌

17. 🔲

18. □

19. 🔲

20.

A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821-1.825.

A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4). Other items or information: Copy of Notice of Missing Requirements enclosed. Surcharge of \$130 was submitted

A second copy of the published International Application under 35 U.S.C. 154(d)(4).

U.S. APPLICATION NO. (If known)			own)	INTERNATIONAL APPLICATION NO.			ATTORNEY'S DOCKET NO.		
10/551,094				PCT/US2004/009384			1033935-000020		
The following fees have been submitted:								DTO LIGHT ONLY	
21. Basic National fee (37 CFR 1.492(a))					(163	1) \$ 300	\$ 0	PTO USE ONLY	
22. Examination fee (37 CFR 1.492(c))						1 2 0			
If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of									
PCT Article 33(1)-(4) (1643) \$ 0						1			
All other situations (1633) \$ 200						\$ 0			
23. Search fee (37 CFR 1.492(b))									
If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article									
33(1)-(4) report prepared by IPEA/OS indicates all claims satisfy provisions of PC1 Article (1640) \$ 0									
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application							j		
to the USPTO as an International Searching Authority (1641) \$ 100									
	International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB (1642) \$ 400								
All other		•			•	2) \$ 500	\$ 0		
TOTAL	OF	21, 22 A	ND 23 =			•	\$ 0		
Additio	nal fe	e for spe	cification	s and drawings filed in pa	aper over 100 she	eets			
(exclud	ding s	equence	listing in	compliance with 37 CFR	1.821(c) or (e) o	r			
Compu				n electronic medium) (37 ch additional 50 sheets o		thereof			
Total Sheets		Sheets	Number	of each additional 50 or fraction	RATE	Tillereor.	-		
0 -100 =	0	/50 =	thereof (round up to a whole number)	x \$ 250	****	-		
		1		any of the search fee, exam		nath or	\$ 0		
declaration aff	er the	date of co	mmencen	nent of the national stage (3)	7 CFR 1.492(h)).		\$ 0		
CLAIMS NUMBER FILED NUMBER EXTRA RATE									
Total claims	Total claims		- 20 =	0	x \$ 50 (1615)		\$ 0		
Independent Claims		0	- 3 =	0	x \$ 200 (1614)		\$ 0		
MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$ 360 (1616)							\$ 0		
TOTAL OF ABOVE CALCULATIONS =							\$ 0		
Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2							0		
SUBTOTAL =							\$ 0		
Processing fee of \$ 130 (1618) for furnishing the English translation later than 30 months from the							0	*****	
earliest claimed priority date (37 CFR 1.492(i)). + TOTAL NATIONAL FEE =									
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied							\$ 0		
by an appropriate cover sheet (37 CFR 3.28, 3.31).\$ 40 per property +									
TOTAL FEES EN	CLOS	ED =					\$		
					.,	Amoun	t to be refunded:	\$	
						Amou	nt to be charged:	\$	
A check in the amount of									
a. A check in the amount of to cover the above fees is enclosed. Please charge my Deposit Account No. 02-4800 in the amount of to cover the above fees. A									
b. duplicate copy of this sheet is enclosed.									
The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any									
overpayment to Deposit Account No. 02-4600. A duplicate copy of this sneet is enclosed.									
d. Charge \$40.00 to credit card. Form PTO-2038 is attached.									
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.									
SEND ALL CORRESPONDENCE TO: Customer No. 21839 SIGNATURE							Sauneiste		
Customer No 21003									
P.O. Box 1404	2312	-1404							
Alexandria, VA 22313-1404 703 836 6620 Mary Katherine Baumeiste						er	26254		
Date: <u>August 4, 2006</u>				-	NAME			STRATION NO.	



United States Patent and Trademark Office

033935-W

UNITED STATES DEPARTMENT OF COMMERCE United States DEPARTMENT OF COMMI United States Patent and Trademark Office A'test COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

U.S. APPLICATION NUMBER NO.

FIRST NAMED APPLICANT

ATTY. DOCKET NO.

10/551.094

Nicholas S Bodor

033935-020

INTERNATIONAL APPLICATION NO. PCT/US04/09384

I.A. FILING DATE

PRIORITY DATE

03/26/2004

03/28/2003

21839 BUCHANAN INGERSOLL PC (INCLUDING BURNS, DOANE, SWECKER & MATHIS) **POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404**

CONFIRMATION NO. 1615 371 FORMALITIES LETTER *OC000000019089459*

Date Mailed: 06/05/2006

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 09/28/2005
- Copy of the International Search Report filed on 09/28/2005
- Preliminary Amendments filed on 09/28/2005
- Request for Immediate Examination filed on 09/28/2005
- U.S. Basic National Fees filed on 09/28/2005
- Assignee Statement for PGPUB filed on 09/28/2005
- Priority Documents filed on 09/28/2005
- Specification filed on 09/28/2005
- Claims filed on 09/28/2005
- Abstracts filed on 09/28/2005
- Drawings filed on 09/28/2005

DOCKETED

The following items MUST be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

• Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Missing Facts Due: 8/5/06

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

A copy of this notice **MUST** be returned with the response.

BARBARA A CAMPBELL

Telephone: (703) 308-9140 EXT 217

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/551,094	PCT/US04/09384	033935-020

FORM PCT/DO/EO/905 (371 Formalities Notice)